EXHIBIT A

12 Person Jury

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

JANE SCHIRMACHER, Plaintiff, -vs- KONINKLIJKE PHILIPS N.V.; PHILIPS RS NORTH AMERICA LLC; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; PHILIPS RS NORTH AMERICA HOLDING CORPORATION; WM. T. BURNETT FOAM LLC; WM. T. BURNETT & CO.; WM. T. BURNETT MANAGEMENT, INC.; WM. T. BURNETT HOLDING LLC; WM. T. BURNETT & CO., INCORPORATED; WM. T. BURNETT FIBER LLC; WM. T. BURNETT IP LLC; AND HEALTH TECHNOLOGY RESOURCES LLC, Defendants.	)	2022L006181 Case No.: Amount: In Excess of Fifty Thousand Dollars ($50,000.00) plus costs.

PLAINTIFF'S COMPLAINT AT LAW

NOW COMES the Plaintiff, Jane Schirmacher, by and through her attorney, David J. Gallagher of MOTHERWAY & NAPLETON, LLP., and complaining of the Defendants Koninklijke Philips, N.V. ("Royal Philips"), Philips RS North America LLC ("Philips RS" or "Respironics"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("Philips USA"), and Philips RS North America Holding Corporation ("Philips RS NA Holding") (hereinafter, collectively referred to as "Philips") and Defendants Wm. T. Burnett Foam LLC ("Burnett Foam"), Wm. T. Burnett & Co. ("Burnett & Co."), Wm. T. Burnett Management, Inc. ("Burnett Management"), Wm. T. Burnett & Co., Incorporated ("Burnett & Co., Inc."), Wm. T. Burnett Holding LLC ("Burnett Holding"), Wm. T. Burnett Fiber LLC ("Burnett Fiber), Wm. T.

Burnett IP LLC ("Burnett IP") (hereinafter, collectively referred to as "Burnett"), and Defendant Health Technology Resources LLC ("Health Technology Resources"), states as follows:

I. THE PARTIES

Plaintiff

1. Plaintiff Jane Schirmacher is and was at all relevant times a resident of Cook County, Illinois. She started using the Philips REMstar CPAP machine in 2012. She continued to use her device until it was recalled and was sent a replacement. The device was provided to her by Health Technology Resources.

Defendants

2. Defendant Koninklijke Philips ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America LLC, Philips Holding USA, Inc., Philips RS North America, and Philips RS North America Holding Corporation. Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention"). Defendant Royal Philips is subject to the jurisdiction and venue of this Court.

3. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

4. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Koninklijke Philips ("Royal Philips"), a Dutch corporation. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is Philips USA.

5. Defendant Philips Holding USA, Inc. ("Philips USA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips USA is a holding company that is the sole member of Defendant Philips NA.

6. Defendant Philips RS North America Holding Corporation ("Philips RS NA Holding") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by Philips USA.

7. Defendant Wm. T. Burnett Foam LLC ("Burnett Foam") is a limited liability company organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Foam may be served through its registered agent at Wm. T. Burnett Management, Inc., 1500 Bush Street, Baltimore, Maryland 21230.

8. Defendant Wm. T Burnett Management, Inc. ("Burnett Management") is a corporation organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Management may be served through its registered agent at Richard B. C. Tucker, Jr., at 1500 Bush Street, Baltimore, Maryland 21230.

9. Defendant Wm. T. Burnett & Co. ("Burnett & Co.") is a corporation owned and operated by Burnett Management and organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230.

10. Defendant Wm. T. Burnett & Co., Incorporated ("Burnett & Co., Inc.") is a textiles corporation organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland, 21230. Burnett & Co., Inc. may be served through its registered agent Richard B. C. Tucker, Jr., at 1500 Bush Street, Baltimore, Maryland 21230.

11. Defendant Wm. T. Burnett Holding LLC ("Burnett Holding") is a limited liability company organized and existing under the laws of the State of Maryland, has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. The Burnett Holding corporate family is comprised of six companies. Burnett Holding may be served through its registered agent at Wm. T. Burnett Management, Inc. at 1500 Bush Street, Baltimore, Maryland 21230.

12. Defendant Wm. T. Burnett Fiber LLC ("Burnett Fiber") is a limited liability company organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Fiber may be served through its registered agent at Wm. T. Burnett Management, Inc., at 1500 Bush Street, Baltimore, Maryland 21230.

13. Defendant Wm. T. Burnett IP LLC ("Burnett IP") is a limited liability company organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett IP may be served through its registered agent at Wm. T. Burnett Management, Inc., at 1500 Bush Street, Baltimore, Maryland 21230.

14. Defendant Health Technology Resources LLC ("Health Technology Resources") is a limited liability company organized and existing under the laws of the State of Illinois and has a principal place of business at 1400 East Lake Cook Road, Suite 170, Buffalo Grove, Illinois 60089. Health Technology Services may be served through its registered agent at CT Corporation System, at 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604.

II. INTRODUCTION

15. Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care.

16. Philips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiPAP) devices for patients with sleep apnea.

17. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

18. On April 26, 2021, as part of its Quarterly Report for Q1 2021, under a section entitled "Regulatory Update," Philips disclosed for the first time that the sound abatement foam in Philips' CPAP, BiPAP, and mechanical ventilator devices posed serious health risks to their users.

19. On June 14, 2021, Philips issued a recall notification for many of its CPAP, BiPAP, and mechanical ventilator devices.

20. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

21. Philips' recall advised that patients using these affected devices of potential risks from exposure to chemicals released from the sound abatement foam via degradation and/or off-gassing.

22. Specifically, Philips' recall notification stated that the risks related to exposure to chemicals given off by the sound abatement foam could include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

23. Upon information and belief, Burnett manufactures the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips' recalled CPAP and BiPAP devices.

24. Upon information and belief, Plaintiff Jane Schirmacher was prescribed the use of and purchased one of Philips' recalled devices, the REMstar CPAP machine, to treat Plaintiff's sleep apnea in 2012 from Health Technology Resources located at 1400 East Lake Cook Road, Suite 170, Buffalo Grove, Illinois 60089.

25. Plaintiff used Philips' REMstar CPAP device (hereinafter, the "Device"), one of Philips' recalled devices, at her home in Cook County on a daily basis for a number of years.

26. After using the device for a number of years, Plaintiff was hospitalized and diagnosed for the first time with glioblastoma on December 31, 2021.

27. As a result, Plaintiff had to go through surgery and receive chemotherapy in order to combat the cancer. The vast majority of the Plaintiff's medical treatment has taken place in Cook County.

28. In addition, Plaintiff also had a deep vein thrombosis ("DVT") which required her to receive an inferior vena cava filter ("IVC").

29. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered serious and substantial life-altering injuries.

30. As a direct and proximate result of the subject device manufactured, marketed, sold, and distributed by Defendants, Plaintiff has suffered physical and emotional injuries, including brain

cancer and the invasive treatment of the cancer and the sequelae of the cancer and its treatment including surgical intervention.

31. Defendants have long known that the polyester-based polyurethane (PE-PUR) sound-abatement foam in Defendants' CPAP, BiPAP, and mechanical ventilator devices has a tendency to release toxic and carcinogenic microparticles that can be inhaled by users like Plaintiff, causing serious injury or death.

32. As a result of the Device's defects and Defendants' tortious acts/omissions, Plaintiff Jane Schirmacher has developed serious and life-threatening conditions and has endured unnecessary pain and suffering.

33. Plaintiff Jane Schirmacher has suffered from unnecessary pain, debilitation, hospitalization, and the development of her glioblastoma and DVT because Defendants defectively designed and manufactured the Device and failed to adequately warn of the dangers of the Device.

III. JURISDICTION AND VENUE

34. Jurisdiction is proper pursuant to 735 ILCS 5/2-209 as at all times relevant hereto, Philips RS was in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, labeling, packaging, marketing, promoting, and/or advertising many of its CPAP, BiPAP, and mechanical ventilator devices throughout the United States including in Cook County, Illinois.

35. At all times relevant hereto, Philips RS was a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania, who routinely conducted business in Cook County, Illinois.

36. Health Technology Resources is a limited liability company organized and existing under the laws of the State of Illinois and has a principal place of business in Buffalo Grove, Illinois, making them residents of Cook County pursuant to 735 ILCS 5/2-102, who routinely conducts business in Cook County, Illinois.

37. Plaintiff Jane Schirmacher on information and belief is a resident of Cook County.

38. Plaintiff has timely filed this lawsuit less than two years from the time Plaintiff knew or reasonably should have known of the injury and that it may have been wrongfully caused.

39. Pursuant to 735 ILCS 5/2-101, venue is proper within this Court because Defendants Philips RS and Health Technology Resources are residents of Cook County, and because Plaintiff was diagnosed and treated for her cancer in Cook County, and the Defendants do business and advertise in this county.

IV. FACTS

40. At all relevant times, Defendants manufactured, sold, and distributed a line of CPAP and BiPAP devices as well as mechanical ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including sleep apnea.

41. Defendants sought and obtained clearance from the Food and Drug Administration ("FDA") to market the recalled devices, including the Device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics Act ("FDCA"). Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicated devices. Obtaining clearance under 510(k) is

significantly less rigorous than through the pre-market approval ("PMA") process, as no formal review for safety or efficacy is performed and no clinical data is required.

A. Continuous Positive Airway Pressure (CPAP) Therapy

42. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device and a CPAP device, which helps individuals breathe by increasing the air pressure in an individual's throat.

43. Sleep apnea is a common sleep disorder affecting millions of Americans, including Plaintiff, and characterized by repeated interruptions in breathing through an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruption, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negative impacts to energy levels, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by forcing pressurized air through the individual's airway, preventing the individual's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure (BiPAP) Therapy

44. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and

involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, in that BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Philips' Sleep & Respiratory Care Devices Were Endangering Users

45. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section titled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP, BiPAP, and mechanical ventilator devices posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including the use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

46. Philips utilized polyester-based polyurethane (PE-PUR) sound abatement foam to dampen device vibration and sound during routine operation.

47. Upon information and belief, Burnett manufactured the PE-PUR foam during the time period that Philips marketed and sold the subject devices.

48. Determined to develop the quietest devices on the market with the lowest possible decibel rating, Philips, with the help of Burnett, filled CPAP and BiPAP devices with sound abatement

foam to reduce the noise emitted from the motor and/or airflow. The design of Philips' CPAP and BiPAP devices, including the subject devices, forces air through and/or over the PE-PUR foam before it is pumped into users' airways, thus exposing users to toxic and carcinogenic byproducts of degradation and off-gassing of the PE-PUR foam.

49. On June 14, 2021, almost two months after Philips notified its stockholders, it finally advised the medical community, medical equipment suppliers and some patients, by issuing a recall notification of specific devices allegedly based upon extensive ongoing review following the announcement on April 26, 2021.

50. In its recall notification, Philips identified examples of potential risks which include exposure to chemicals emitted from the sound abatement foam material via degradation and/or off-gassing.

51. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms, and complications, as well as possibly serious injury, which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

52. According to Philips' recall notice, the PE-PUR foam used in recalled devices such as the Device used by Plaintiff puts users at risk of suffering from the following health harms: "headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects."

53. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In that report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

-Toluene Diamine

-Toluene Diisocyanate

-Diethylene glycol."

54. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips had also identified the presence of Volatile Organic Compounds (VOCs) which may be emitted from the sound abatement foam component of the affected devices, stating "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

-Dimethyl Diazine

-Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-

D. Philips' Recalled Devices

55. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.

56. The list of devices recalled by Philips (the "Recalled Devices") include:

Philips CPAP and BiPAP Devices Subject to Recall	
Philips Device Name/Model	**Type**

Philips E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips DreamStation ASV	Continuous Ventilator, Non-life Supporting
Philips DreamStation ST, AVAPS	Continuous Ventilator, Non-life Supporting
Philips SystemOne ASV4	Continuous Ventilator, Non-life Supporting
Philips C Series ASV, S/T, AVAPS	Continuous Ventilator, Non-life Supporting
Philips OmniLab Advanced Plus, In-Lab Titration Device	Continuous Ventilator, Non-life Supporting
Philips SystemOne (Q Series)	Non-continuous Ventilator
Philips DreamStation, CPAP, Auto CPAP, BiPAP	Non-continuous Ventilator
Philips DreamStation GO, CPAP, APAP	Non-continuous Ventilator
Philips Dorma 400, 500, CPAP	Non-continuous Ventilator
Philips REMStar SE Auto, CPAP	Non-continuous Ventilator

Philips Device Name/Model	**Type**
Philips Trilogy 100 Ventilator	Continuous Ventilator
Philips Trilogy 200 Ventilator	Continuous Ventilator
Philips Garbin Plus, Aeris, LifeVent Ventilator	Continuous Ventilator
Phiips A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto Ventilator	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	Continuous Ventilator, Non-life Supporting

57. Philips issued the following advice to patients using any of the recalled devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."

- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."

E. Philips Unreasonably Delayed the Recall

58. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." However, given how long ago the first of the recalled devices came to market, it is likely that Defendant learned of these issues for a substantial period of time before the recall. Additionally, Philips released its next-generation CPAP device, the DreamStation 2, which does not have the defective, carcinogenic foam, on April 13, 2021 – not even two full weeks before Philips first publicly disclosed in its Q1 2021 Quarterly Report a potential health issue with its CPAP devices, including Plaintiff's REMstar CPAP device. Defendants first sought FDA clearance for the DreamStation 2 in February 2020, and in all likelihood began developing it long before then.

59. Thus, as a result of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation and off-gassing of the PE-PUR sound abatement foam used in the recalled devices, including Plaintiff's Device, yet continued to manufacture, market, and sell the recalled devices with such cognizance for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the recalled devices and unreasonably put users of the recalled devices at risk of developing adverse health effects, including cancer.[1]

60. Upon information and belief, Burnett knew about the possibility of PE-PUR foam degradation since it began manufacturing the foam for Philips CPAP and BiPAP devices.

[1] Department of Health and Human Services. (Nov. 9, 2021). *Form FDA 483*. Retrieved Dec. 15, 2021, from https://www.fda.gov/media/154099/download.

61. Upon information and belief, Burnett continued to manufacture the PE-PUR foam after being notified of the risks of foam degradation.

62. Upon information and belief, Philips knew about the possibility of PE-PUR foam degradation since it began using this particular foam in its CPAP and BiPAP devices.

63. Upon information and belief, Philips knew about the possibility of PE-PUR foam degradation since or before it began researching or developing the DreamStation 2 device.

64. Upon information and belief, Philips knew of the risk that incorporating PE-PUR foam in the air pathway of the subject devices could result in users ingesting or inhaling toxic and carcinogenic particulates and VOC gas emissions.

65. Philips should have known of the risk that degraded PE-PUR foam could produce toxic and carcinogenic particulates and VOC gas emissions, and that incorporating PE-PUR foam in the air pathway of the recalled devices could expose users to the risk of ingesting or inhaling toxic and carcinogenic particulates and VOC gas emissions.

66. An adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Respironics learned that a patient reported discovering "black dust" on her nose when she awoke the morning after using a REMstar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness." Philips investigated this report and confirmed the device contained "evidence of an unknown black substance in the air path and on internal components ... present throughout both the intake and exhaust portions of the airpath." However, Philips denied that the presence of the black substance was due to a product defect.

67. Plaintiff was prescribed and purchased a Philips REMstar CPAP device in 2012.

PLAINTIFF'S REMSTAR CPAP DEVICE

68. Plaintiff brings this product liability personal injury action as a recipient of defective medical devices, i.e., a CPAP device designed, manufactured, and distributed by Defendants.

69. In 2012, Plaintiff was prescribed and purchased a Philips REMstar CPAP device.

70. Defendants, directly or through their subsidiaries or affiliates, designed, manufactured, distributed, and sold the Philips REMstar CPAP device prescribed to and purchased by Plaintiff.

71. Based upon the patient population that Defendants intended its Philips REMstar CPAP device to be used by, when Plaintiff used the Device, Plaintiff was an appropriate patient to use the Device.

72. At all times subsequent to the date of first use, Plaintiff used the Device in a normal and expected manner.

73. At the time the Device was purchased by Plaintiff, it was in the same condition in all relevant respects as when it left Philips' control.

74. Prior to Plaintiff's purchase of the Device, Philips did not warn patients, including Plaintiff, physicians, its customers, or its sales representative/distributors that the Device was known to emit toxic and/or carcinogenic particles from its PE-PUR sound abatement foam via degradation and/or off-gassing, which could then be directly inhaled by the user, causing severe injury or death.

75. Plaintiff's use of the Device has subjected Plaintiff to much greater risks of future harm than Plaintiff had before using the Device.

76. Had Plaintiff or Plaintiff's physician known that the Device would release carcinogenic particles causing Plaintiff's glioblastoma and DVT, then neither Plaintiff nor Plaintiff's physician or medical supplier would have chosen the Device for treatment of Plaintiff's sleep apnea.

77. As a direct and proximate result of use of Philips' REMstar CPAP device, Plaintiff has suffered significant harm, including but not limited to:

a) the development of glioblastoma and attendant hospitalizations;

b) the development of a deep vein thrombosis which required her to receive an inferior vena cava filter;

c) past and future pain and anguish, both in mind and in body;

d) permanent diminishment of Plaintiff's ability to participate in and enjoy the affairs of life;

e) medical bills associated with the treatment of glioblastoma and deep vein thrombosis and recovery therefrom;

f) future medical expenses;

g) loss of enjoyment of life;

h) disfigurement; and

i) physical impairment.

FEDERAL STATUTORY AND REGULATORY REQUIREMENTS

78. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal requirements. 21 U.S.C. § 351.

79. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 352.

80. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360(i).

81. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packaging, storage and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law.

82. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 820, et seq. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to

use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

83. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Drug & Cosmetic Act ("the Act"). 21 U.S.C. § 351.

84. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. 21 C.F.R. § 820.3(v).

85. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

86. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

87. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

88. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

89. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

90. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

91. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

92. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation.

93. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a) documented instructions, standard operating procedures (SOPs) and methods that define and control the manner of production;

b) monitoring and control of process parameters and component and device characteristics during production;

c) compliance with specified reference standards or codes;

d) the approval of processes and process equipment; and

e) criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

94. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

95. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

96. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on produce quality.

97. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

98. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

99. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

100. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

101. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. § 820.3(z)(1).

102. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

103. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

104. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a) analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems;

b) investigating the cause of nonconformities relating to product, processes, and the quality system;

c) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d) verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f) ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g) submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

105. Upon information and belief, Defendants' REMstar CPAP device is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

106. Upon information and belief, Defendants' REMstar CPAP device is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

107. Upon information and belief, Defendants' REMstar CPAP device is adulterated pursuant to 21 U.S.C. § 351 because Philips failed to establish and maintain CGMP for its REMstar CPAP device in accordance with 21 C.F.R. § 820, *et seq.*, as set forth above.

108. Upon information and belief, Philips failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for the recalled devices, including the Philips REMstar CPAP device.

109. As a result of Philips' failure to establish and maintain CGMP as set forth above, Philips' REMstar CPAP device was defective, resulting in injuries to Plaintiff.

110. If Philips had complied with the federal requirements regarding CGMP, Philips' REMstar CPAP device would have been manufactured and/or designed properly such that it would not have resulted in injuries to Plaintiff.

V. CLAIMS

COUNT I
STRICT LIABILITY (DEFECTIVE DESIGN)

111. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

112. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Philips REMstar CPAP device as hereinabove described that was prescribed to and used by Plaintiff.

113. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Philips REMstar CPAP device so that it was neither defective nor unreasonably dangerous when used for which it was designed, manufactured, distributed, marketed, and sold.

114. At all times herein mentioned, the Philips REMstar CPAP device was in an unsafe, defective, and inherently dangerous condition for users such us Plaintiff.

115. At all times of use of the Device by Plaintiff, the Device was being used for the purposes and in a manner normally intended, namely for use as treatment for sleep apnea.

116. At the time the Devices left the possession of Defendants and the time the Philips REMstar CPAP devices entered the stream of commerce, they were in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

a) the Devices were not reasonably safe as intended to be used;

b) the Devices had an inadequate design for the purpose of treatment of sleep apnea, in that the sound abatement foam should not release toxic and carcinogenic particles and should not have been placed in the device's airpath where such particles would then travel directly into patients' lungs and bodies;

c) the Devices contained unreasonably dangerous design defects, including an inherently defective design, i.e., placement of a sound abatement foam that releases toxic and

carcinogenic particles directly in the airpath of the Device, from where such particles could easily travel to the user;

d) the Devices defective design resulted in a CPAP device which had risks that far exceeded the benefits of the medical device;

e) the Devices were not appropriately or adequately tested before their distribution; and

f) the Devices have an unreasonably high propensity for the release of toxic and carcinogenic particles under normal and expected use of the Devices.

g) The Devices have built-in settings for heat and humidity that are expected to be utilized during normal use, and according to Philips such environmental factors may exacerbate the release of toxic and carcinogenic particles from the sound abatement foam in the Devices.

117. At all times herein mentioned, the Devices were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

118. The Philips REMstar CPAP device's unsafe, defective, and inherently dangerous conditions were the cause of injury to Plaintiff.

119. The Devices failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

120. Plaintiff's injuries resulted from use of the Device that was both intended and reasonably foreseeable by Defendants.

121. At the time of Defendants' initial design, manufacture, marketing and sale of the Devices, a feasible, alternative safer design for the Devices was known and available to Philips.

122. At the time of and subsequent to Defendants' initial design, manufacture, marketing and sale of the Devices, including prior to the time of Plaintiff's initial purchase and use of the Device, Defendants had the ability to eliminate the unsafe character of the Devices without impairing their usefulness, as by either using non-toxic, non-carcinogenic sound abatement foam, or by simply placing the sound abatement foam anywhere else in the Device besides the Device's airpath, among other reasonable alternatives.

123. Had Defendants properly and adequately tested the Devices; Defendants would have discovered that the sound abatement foam had a high propensity for releasing toxic and carcinogenic particles when used normally by patients.

124. The Philips REMstar CPAP devices, manufactured and supplied by Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Devices' particular design or formulation, and/or it was unreasonably dangerous to the user or consumer, and/or it failed to comply with federal requirements for these medical devices.

125. The foreseeable risks associated with the design or formulation of the Philips REMstar CPAP devices include, but are not limited to, the fact that the design or formulation of these devices are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

126. At all times herein mentioned, the Defendants knew, or should have known, that the Devices were in a defective condition, and were inherently dangerous and unsafe for use.

127. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

128. As a direct and proximate result of Plaintiff's use of Defendants' REMstar CPAP devices, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or their failure to comply with federal requirements, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

129. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

130. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, marketing, and sale of the Philips REMstar CPAP device.

131. Defendants designed, manufactured, assembled, and sold the Philips CPAP device to medical distributors and patients knowing that they would then be used by patients to treat sleep apnea.

132. The Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings because Defendants knew or should have known that the Device could release toxic and/or carcinogenic particles in patients when used and therefore gives rise to serious physical injury, pain and suffering, debilitation, and death, but failed to give consumers adequate warning of such risks.

133. Defendants had a duty to warn their sales representatives/distributors, prescribing sleep doctors, and patients such as Plaintiff, and Defendants breached their duty in that they failed to provide adequate and timely warnings or instructions regarding their Philips REMstar CPAP device, and its known defects and potential risks, including its propensity to release toxic and/or carcinogenic particles when used normally.

134. Adequate efforts to communicate an adequate warning to the ultimate users were not made by Defendants (or Defendants' sales representatives/distributors).

135. Defendants are strictly liable to Plaintiff because the warnings to Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's prescribing physician about the dangers the Philips REMstar CPAP device posed to consumers when used were inadequate. Examples of the lack and/or inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

a) the Devices contained warnings insufficient to alert Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's physicians as to the risk of adverse events, i.e., respiratory issues, development of disease like cancer, and even death, associated with use of the Philips REMstar CPAP device, subjecting the Plaintiff to risks which exceeded the benefits of the Devices;

b) the Devices contained warnings insufficient to alert Plaintiff and Plaintiff's physicians as to the release of toxic carcinogenic particles when used normally;

c) the Devises contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with its use, thereby making use more dangerous than the ordinary consumer would expect;

d) the Devices contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, the medical supplier, and the prescribing physicians, regarding the risk, scope, propensity, frequency, duration, and severity of the adverse events associated with use of Device;

e) the Devices did not disclose that they were inadequately tested;

f) the Devices failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope, and/or duration of the dangers posed by normal use of the Devices to treat sleep apnea;

g) the Devices failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

136. Further, Philips REMstar CPAP device is unreasonably dangerous because it was sold to Plaintiff without an adequate warning that when used normally, the PE-PUR sound abatement foam will release toxic and carcinogenic particles that can lead to serious injury or death.

137. There are other manufacturers of sleep apnea machines on the market that do not contain this foam design defect and Plaintiff could have chosen to acquire a different model and brand had this defect been disclosed.

138. The Devices placed into the stream of commerce by Defendants were used by patients like Plaintiff in a manner reasonably anticipated by Defendants.

139. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
STRICT PRODUCTS LIABILITY
(MANUFACTURING DEFECT) AND
(FAILURE TO ADHERE TO QUALITY CONTROLS)

140. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

141. The recalled devices, including Plaintiff's Device, are defectively manufactured because the foreseeable risks of cancer and other serious injury and illness outweigh the benefits associated with the Devices.

142. The Philips REMstar CPAP Device was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by defendants in the manufacture, testing, packing, storage, or installation of the Devices were not in conformity with applicable requirements of the FDCA.

143. The Philips REMstar CPAP device was expected to and did reach the Plaintiff without substantial change or adjustment to its function.

144. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Philips REMstar CPAP device.

145. Furthermore, the Philips REMstar CPAP Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

146. The Philips REMstar CPAP Device is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to the Plaintiff for their breach of duty to the Plaintiff.

147. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff has sustained and will continue to sustain severe physical injuries, and the Plaintiff has suffered and will continue to suffer severe emotional distress, mental anguish, and other damages for which Plaintiff is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

148. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

149. While the focus of Plaintiff's strict liability claims (Claims I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality

assurance, quality control, labeling, warning, sale and/or distribution of the Philips REMstar CPAP device, including a duty to assure that their products did not pose a significantly increased risk of life-threatening bodily harm and disease.

150. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions, and distribution of the Philips REMstar CPAP device in that Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

151. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a) Negligently designing the recalled devices' PE-PUR sound abatement foam such that it has a high propensity to release toxic and carcinogenic particles during normal use of the device;

b) Negligently designing the recalled devices such that the sound abatement foam is placed in the airpath of the devices, where the foam's propensity to release toxic and carcinogenic particles is most deleterious to a patient's health because they will directly inhale such toxins and carcinogens;

c) Negligently designing the recalled products such that they contain built-in settings for use that allow a user to increase the heat and humidity of the air being convected through the devices' airpaths, despite Defendants knowing that heat and humidity can exacerbate the release of the toxic and carcinogenic particles from the PE-PUR sound abatement foam;

d) Designing, manufacturing, producing, creating, and/or promoting the devices for use in treating sleep apnea without adequately, sufficiently, or thoroughly testing them, including both pre-market testing and post-market surveillance;

e) Not conducting sufficient testing programs to determine whether or not the PE-PUR sound abatement foam was safe for use in the devices;

f) Selling the devices without making proper and sufficient tests to determine the dangers when used in a reasonably foreseeable and normal manner;

g) Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals, healthcare providers, and medical device distributors of the dangers of using the recalled devices, including:

i. Negligently failing to warn of an increased risk of release of toxic and carcinogenic particles;

ii. Negligently failing to warn of the risk of development of serious disease such as cancer or even death;

iii. Negligently failing to recall their dangerous and defective CPAP devices at the earliest date it became known that the devices were, in fact, dangerous and defective;

iv. Negligently advertising and recommending the use of the devices despite the fact Defendants knew or should have known of their dangerous propensities;

v. Negligently representing that the devices were safe for their intended use, when in fact, they were unsafe;

vi. Negligently manufacturing the devices in a manner which was dangerous to those individuals who used them;

h) Defendants under-reported, underestimated, and downplayed the serious dangers associated with the PE-PUR sound abatement foam used in all of the recalled devices;

i) Defendants failed to use due care in designing and manufacturing the devices so as to ensure good performance and durability and reduce the risk of degradation and off-gassing of toxic and carcinogenic particles that could be directly inhaled by the user;

j) Failed to accompany their products with proper warnings;

k) Failed to accompany their products with proper instructions for use;

l) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the recalled devices when used normally;

m) Were otherwise careless and/or negligent.

152. Despite the fact that Defendants knew or should have known that use of the Philips REMstar CPAP device caused harm to individuals that used the devices, Defendants continued to market, manufacture, distribute and/or sell the Philips REMstar CPAP device for use in treating sleep apnea.

153. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

154. Defendants, furthermore, in advertising, marketing, promoting, packaging, and selling the Devices negligently misrepresented material facts regarding their safety, efficacy and fitness for

human use by claiming the Devices were fit for their intended purpose of use when, in fact, they were not.

155. Defendants' negligence was the proximate cause of Plaintiff's physical, mental, and emotional injuries and harm, and economic loss which Plaintiff has suffered and/or will continue to suffer.

156. By reason of the foregoing, Plaintiff experienced and will continue to experience severe harmful effects as a result of the Defendants' negligence as set forth above.

157. Defendants' conduct, as described above, including, but not limited to, Defendants' failure to adequately test and warn, as well as their continued marketing and distribution of the Philips REMstar CPAP device devices when they knew or should have known of the serious health risks these devices created when used normally by patients such as Plaintiff.

158. As a direct and proximate result of Defendants' negligence, including negligent testing, failure to warn and misrepresentations, Plaintiff suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm and damages for which Plaintiff is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT MISREPRESENTATION

159. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

160. Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Philips REMstar CPAP device. Defendants provided this false information to induce the public, Plaintiff and Plaintiff's physicians to purchase and use the Philips REMstar CPAP device.

161. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the Devices would induce Plaintiff and Plaintiff's physicians to purchase and use the Philips REMstar CPAP device was false and misleading.

162. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Philips REMstar CPAP device.

163. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment by causing the Philips REMstar CPAP device to be purchased and used by Plaintiff.

164. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the Philips REMstar CPAP device.

165. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, and pain and suffering caused by the Philips REMstar CPAP device.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY
(810 ILCS 5/2-313)

166. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

167. Defendants expressly warranted that the Philips REMstar CPAP device was a safe and effective medical device to be used for patients suffering from sleep apnea.

168. At the time Defendants marketed, sold and/or distributed the Philips REMstar CPAP device, they knew that the Devices were intended for human use, and that Plaintiff was a foreseeable user of the Devices.

169. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Device, and Plaintiff and Plaintiff's physician relied on these warranties in deciding to use the Device.

170. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Devices were to be used and warrantied the same to be in all respects safe, effective, and proper for such purpose.

171. The Devices do not conform to these express representations as shown by the development of brain cancer in Plaintiff.

172. At the time Defendants marketed, sold and/or distributed the recalled devices, Defendants expressly warranted that the recalled devices were safe for their intended use.

173. Plaintiff and Plaintiff's prescribing physician reasonably relied upon Defendants' express warranties.

174. Plaintiff used the Device for its intended purpose, and in a reasonably foreseeable manner.

175. The Philips REMstar CPAP device manufactured and sold by Defendants did not conform to Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

176. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future and is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FOR A PARTICULAR PURPOSE
(810 ILSC 5/2-314)

177. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

178. At the time Defendants designed, manufactured, marketed, sold, and distributed the Philips REMstar CPAP device for use by Plaintiff, Defendants knew of the use for which these devices were intended and impliedly warranted these products to be of merchantable quality and safe for such use and that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.

179. The Philips REMstar CPAP device manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risks included an unreasonably high risk of developing cancer or other serious illness due to the release of toxic and carcinogenic particles from the device's PE-PUR sound abatement foam.

180. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the Philips REMstar CPAP device were of merchantable quality and safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters.

181. Contrary to such implied warranties, the Philips REMstar CPAP device was not of merchantable quality or safe for its intended and particular use and purpose, because the product was defective when used normally as described above, and/or failed to comply with federal requirements.

182. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future and is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(810 ILSC 5/2-315)

183. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

184. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Philips REMstar CPAP device.

185. At the time Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Philips REMstar CPAP device, Defendants knew the use for which the Philips REMstar CPAP device was intended, and impliedly warranted the Philips REMstar CPAP device to be safe for such use.

186. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the Philips REMstar CPAP device were safe for its intended use.

187. Contrary to Defendants' implied warranties, the Philips REMstar CPAP device was not fit for its intended and particular use and purpose, because the device was defective when used as described above, and/or failed to comply with federal requirements.

188. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future and is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

(815 ILSC 505/1, *et seq.*)

189. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

190. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Philips REMstar CPAP device as a high-quality, safe, and effective medical device for treatment of sleep apnea to Plaintiff and Plaintiff's physicians.

191. Before they advertised, marketed, sold, and represented the Philips REMstar CPAP device that were used by Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a device posed to patients like Plaintiff.

192. Plaintiff purchased and used the Philips REMstar CPAP device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

193. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Philips REMstar CPAP device and would not have incurred related medical costs and injury.

194. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Philips REMstar CPAP device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

195. Unfair methods of competition or deceptive acts or practices that are proscribed by law, include the following:

a) Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

196. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Philips REMstar CPAP device. Each aspect of Defendants' conduct combined to artificially create sales of the Philips REMstar CPAP device.

197. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Philips REMstar CPAP device.

198. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Philips REMstar CPAP device and would not have incurred related medical costs.

199. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statute listed.

200. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts, or trade practices in violation of state consumer protection statute, as listed below.

201. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, (815 ILSC 505/1, *et seq.*).

202. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

203. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Philips REMstar CPAP device were fit to be used for the purpose for which they were intended, when in fact these devices were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

204. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

205. Defendants had actual knowledge of the defective and dangerous condition of the Philips REMstar CPAP device and failed to take any action to cure such defective and dangerous conditions.

206. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which CPAP / sleep apnea treatment device to use and recommend.

207. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

208. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

209. As a direct and proximate result of Defendants' violations of Illinois consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

210. As specifically described in detail above, Defendants knew that the Philips REMstar CPAP device subjected patients to the release of toxic and carcinogenic particles leading to serious illness, injury, and even death.

211. As a direct and proximately result of Defendants' representations, Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for continued medical treatment and observation to monitor the physical damage to Plaintiff caused by the Philips REMstar CPAP device.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
PUNITIVE DAMAGES

212. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

213. Defendants risked the safety of recipients of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

214. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of its recalled devices despite knowledge that these devices were defective and unreasonably dangerous in nature.

215. Defendants knew or ought to have known that this conduct would result in injury or damage but continued to mislead both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the recalled devices.

216. These acts are wanton and reckless in that the Defendants demonstrated conscious indifference and utter disregard of the consequences of their actions upon the health, safety, and rights of others, including Plaintiff.

217. Additionally, Defendants delayed the recall of the defective devices while seeking clearance for the next-generation DreamStation 2 CPAP device, which is significantly more expensive than the recalled first-generation devices and did not disclose to the public any of the risks described herein until after the DreamStation 2 had been made commercially available. Thus, Defendants allowed patients like Plaintiff to continue to be exposed to toxic and carcinogenic particles for a significantly longer period of time while Defendants were attempting to monetize this public health crisis of their own creation.

218. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, Plaintiff suffered severe and permanent physical injuries as set forth above. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against defendants for compensatory, treble, and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems proper.

By: David J. Gallagher

MOTHERWAY & NAPLETON, LLP.
Attorneys for Plaintiff
140 S. Dearborn, Suite 1500
Chicago, IL 60603
(312) 726-2699 - PHONE
(312) 726-6851 - FAX
Atty. No. 56421
dgallagher@mnlawoffice.com